

**REMARKS**

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections based on the foregoing amendments and following remarks. Claims 1-29 have been amended to recite method claims. Support for these amendments can be found in the present specification at page 3, line 35 to page 4, line 1 and at Example 2 at pages 7 and 8. Claim 1 has also been amended to recite the specific melatonin derivatives listed at pages 1 and 2 of the present specification and to include the limitation of claim 4, whereby claim 4 has been cancelled. Claim 29 has also been cancelled. Claim 10 has been amended to remove the phrase “or another derivative of vitamin A.” New method of treatment claims 30 and 31 have been introduced and support for these new claims can be found in the present specification at paragraph 0012-0014. No new matter has been added.

Claims 1-29 stand rejected under 35 U.S.C. 112, first paragraph. Claim 1 has been amended to recite the specific melatonin derivatives 5-methoxytryptamine, 5-methoxytryptophan, 5-methoxytryptophol, 5-methoxyindole-3-acetic acid and 6-hydroxymelatonin. Claim 10 has been amended to remove the phrase “or another derivative of vitamin A.” Accordingly, Applicants submit that present claims 1-29 are now in condition to satisfy the requirements of 35 U.S.C. 112, first paragraph.

Applicants would like to draw the Examiner’s attention to a limitation added to present claim 1, specifically, the recitation of “salts and esters thereof.” While this limitation has not been examined as of yet, Applicants wish to state that the terms

"salts" and "esters" of active ingredients such as melatonin and melatonin derivatives belong to common knowledge to a person skilled in the art. In order to support our statement, Applicants hereby submit, as Appendix A, excerpts of the chemical lexicon Roempp. This document provides generally accepted definitions of the terms "salts" and "esters". Accordingly, *salts* are defined as "heteropolar compounds having a crystal lattice which comprise at least one type of cation being different from hydrogen ions (protons) and at least one type of anion being different from hydroxide ions." Accordingly, *esters* are defined as "a group of carboxylic acid derivatives, which also include esters of inorganic acids such as sulfuric acid, nitric acid, nitrous acid, phosphoric acid and boric acid."

Claims 1-22 and 26-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Dirksing (USP 5,006,004) in view of Samples (USP 4,654,361) and Kosbab (US Published Patent Application 2001/0031744). Applicants submit that the Examiner has not provided adequate motivation to establish a prima facie case of obviousness for at least the following reasons.

Dirksing discloses a dispenser for topical application of a liquid for restoring hair growth. The dispenser of Dirksing can be for single use for the delivery of single doses (see column 2, lines 38-39). The liquid is applied by compression of a reservoir, which causes the liquid contained therein to flow to the surface of the applicator tip. Then, the liquid is applied to the sites to be treated by contacting said sites with the applicator tip.

Samples discloses the use of melatonin for lowering intraocular pressure. Although it is formally disclosed that the substance can be applied topically, the

examples given in Samples only pertain to oral administration. Example 3 discloses the administration of melatonin as a single dose, which corresponds to a daily dose. Furthermore, Samples do not disclose the use of a disposable container nor a liquid formulation contained therein.

Kosbab discloses compositions for treating multiple diseases selected from diabetic retinopathy and nephropathy including macular degeneration, cataract, glaucoma, wound healing, neuropathy, cardiovascular disease and dental or periodontal diseases. While melatonin is not mentioned in this document, compositions are disclosed which comprise, beyond multiple other active ingredients, a combination of ginkgo biloba with vitamin A for treating diabetic complications of microangiopathy (see claims 7 and 8). Further, a formulation 1E, which contains vitamin A (acetate or palmitate) among other active substances (see paragraph [0045]), and diabetic formulations IIIA and IIIE are disclosed, which contain among other active ingredients a combination of ginkgo biloba with biotin or a combination of vitamin A with biotin (see paragraph [0172] to [0222]).

The subject-matter of the present claims differs from Dirksing in that Dirksing does not disclose a disposable container which includes a single total daily dose of melatonin for topical application. The advantages of a container comprising a total dose of melatonin which is applied only one time per day instead of several times reside in a higher compliance for the patients as well as a higher therapy efficiency. Furthermore, the patients are less burdened with cost and time with respect to the therapy. Additionally, the cost of packaging the medicament is lowered.

Thus, the subject matter of the present claims is directed to a method for topical

application of melatonin to the scalp and/or hair, which enables a convenient, reliable and efficient therapy with reduced expenses of time and costs for the patients. The subject matter of the present claims provides a method of using a disposable container that includes a single daily dose of melatonin.

From the disclosures of Samples and/or Kosbab, a person skilled in the art would not have arrived at the subject matter of the present claims. Although Samples discloses in Example 3 the administration of a single daily dose melatonin, the examples do not concern a method for topical administration of melatonin at all, let alone to the scalp or hair. Furthermore, no container is disclosed in Samples for administration of melatonin. Thus, Samples teaches away from the subject-matter of the present claims by teaching a method for oral application of melatonin without a container involved in the administration.

With respect to Kosbab, a person skilled in the art would not have motivation to combine the teachings of Kosbab with Samples or Dirksing to arrive at the subject matter of the present claims, as Samples is silent with respect to a method for topical application of a single daily dose of melatonin to the scalp and/or hair by using a container. Samples also does not teach advantages resulting therefrom with respect to convenient, reliable and efficient melatonin therapy with reduced expense and time for the patient.

A person skilled in the art would not have considered the use of the container described in Dirksing for applying the compositions disclosed in Samples or Kosbab. The liquid in the container of Dirksing is applied by pressing the applicator tip to the surface to be treated. Such a container would not be appropriate to transfer a

composition of Samples to the eyes, as pressing the applicator tip to the eye surface clearly conflicts with the purpose disclosed in Samples, i.e. to reduce intraocular pressure.

For the reasons described above, Applicants respectfully submit that one of skill in the art would not have had adequate motivation to combine the disclosures of Dirkseng, Samples and Kosbab to arrive at the subject matter of the present claims. Thus, the combination of Dirkseng, Samples and Kosbab does not and can not render obvious the present claims.

Claims 23-25 and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable over Dirksing et al. (USP 5,006,004) in view of Samples et al (USP 4,654,361), Kosbab (US Published Patent Application 2001/0031744) and Fukuoka (USP 5,577,636). Applicants submit that the Examiner has not provided adequate motivation to establish a prima facie case of obviousness.

Applicants submit that claims 24, 25 and 29 are dependent upon claim 23, which is dependent upon claim 1. Accordingly, the arguments as made above with respect to Dirkseng, Samples and Kosbab apply here and will not be repeated. Fukuoka teaches a multi-tube container comprising multiple tubes that are breakable and attached to each other. Fukuoka is silent with respect to a container containing melatonin for use in restoring hair growth. Therefore, Fukuoka does not cure the noted deficiencies of the combination of Dirkseng, Samples and Kosbab.

For the reasons described above, Applicants respectfully submit that one of skill in the art would not have had adequate motivation to combine the disclosures of Dirkseng, Samples and Kosbab to arrive at the subject matter of the present claims.

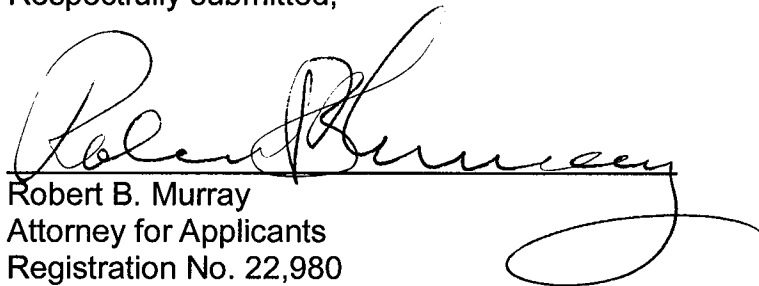
The addition of the Fukuoka disclosure does not cure these noted deficiencies.

Claims 1-29 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same subject matter as in co-pending, published U.S. Patent Application No. 10/353,056. Applicants respectfully submit that the present amendments to claims 1-29 now renders this rejection moot. Present claims 1-29 recite method claims, whereas U.S. Patent Application No. 10/353,056 is directed to product claims. Based on this, Applicants submit that there can no longer be overlapping subject matter between the present claims and U.S. Patent Application No. 10/353,056.

In view of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the outstanding Office Action rejections. Early and favorable action is awaited. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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**Appendix A**

Appendix is attached to this Amendment as separate sheets.